

**F A X C O V E R**

*****OFFICIAL FAX*****

Date: August 14, 2003 **Number of pages (including cover):** 7

To: Examiner Carol M. Koslow, U.S. Patent and Trademark Office

Fax No.: 703-872-9601

Serial No.: 10/044,801

Title: NANOCRYSTALLINE APATITES AND COMPOSITES, PROSTHESIS INCORPORATING THEM, AND METHOD FOR THEIR PRODUCTION

From: Timothy J. Oyer, Ph.D.

Direct dial: 617.573.7851

Our File #: M00925.70110.US

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DOCKET NO.: M00925.70110.US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Jackie Y. Ying et al.
 Serial No: 10/044,801
 Confirmation. No.: 4734
 Filed: January 11, 2002
 For: NANOCRYSTALLINE APATITES AND COMPOSITES,
 PROSTHESIS INCORPORATING THEM, AND METHOD FOR
 THEIR PRODUCTION
 Examiner: Carol M. Koslow
 Art Unit: 1755

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.6(d)

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 Signature

Commissioner For Patents
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Sir:

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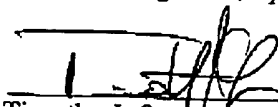
☒ Submission to Examiner

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500, Boston, Massachusetts.

A check is not attached. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,
 Jackie Y. Ying et al., Applicants

By:


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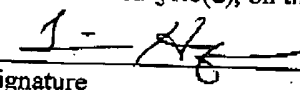
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Alexandria, VA 22313-1450

SUBMISSION TO EXAMINER

The Applicants appreciate the courtesy of Examiner Koslow in allowing the Applicants, through the undersigned and Gordon Coons, Esq. (Reg. No. 20,821), to conduct a telephone interview in connection with the above-identified application on August 13, 2003. It is the understanding of the undersigned that Examiner Koslow will prepare, for the record, a summary of the interview. If this is incorrect, and the undersigned is expected to provide or supplement such a summary (and this submission does not fulfill that obligation), then it is requested that the Examiner inform the undersigned.

During the interview of August 13, 2003, the undersigned, Mr. Coons, and Examiner Koslow discussed a proposal for responding to the outstanding Final Office Action dated June 3, 2003 in this application. Proposed amended claims are provided at the end of this document, as well as claims 1 and 11 as filed in the patent application resulting in the issued patent of which this application is a reissue.

At the outset, the undersigned and Mr. Coons suggested a way of removing all prior art rejections. It is believed that those proposals were well-received and, if followed by a

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corresponding response including the claim amendments attached, should result in withdrawal of all art rejections.

The rejection of various claims under 35 U.S.C. §251 (recapture) was also discussed in the context of the case law cited by the Examiner (*In re Clement*, 131 F.3d 1464, 45 USPQ 2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States* 729 F.2d 1429, 221 USPQ 289 (Fed. Cir. 1984); and *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ 2d 1641 (Fed. Cir. 1998)), as well as MPEP §1412.02, relevant to recapture.

The undersigned and Mr. Coons presented an analysis of the existing case law, and corresponding treatment of the issue at MPEP §1412.02, and applied this analysis both to the pending claims and to the claims as proposed for amendment. The Applicants' position in this regard appears also to have been well-received by Examiner Koslow. Examiner Koslow requested that the Applicants submit a written summary of their position for her benefit in considering the issue internally within the Patent Office. This submission comprises that summary. It is not intended to be a response to the outstanding Final Office Action, but is intended to be made of record as part of the file history of this application in accordance with Patent Office rules that facilitate accessibility, to the public, of the subject matter of all communication between the Patent Office and applicants for patents.

The decision pathway regarding reissue applications, specifically regarding recapture

In the analysis discussed below, an important distinction exists between whether reissue claims must be compared to claims *issued in the original patent* from which the reissue derives (hereinafter, "original patent claims"), or to *claims of the original application*, later cancelled or amended to obtain the original patent (hereinafter, "pre-amendment application claims"; generally referred to in the case law and MPEP as "cancelled", "amended", or "original" claims). For this discussion concerning pre-amendment application claims, it is noted that the case law equates an original claim that is amended during prosecution for allowance, with a canceled claim replaced by a substitute claim of different scope for allowance. In the application resulting in the original patent here, claims were not cancelled and replaced. Rather, independent composition claims 1 and 11 were amended substantively during prosecution (amendment of June 21, 1999). These were the only claims that were substantively amended. Thus, Claims 1 and 11, as filed in the original application, constitute the only "pre-amendment application claims."

The first step in analysis of a claim applied for in a reissue application is whether or not the reissue claim is broader than the corresponding *original patent claim*. If the reissue claim is broader, then the reissue application must be filed within two years of the issue date of the patent, and a basis for error in not pursuing the broader claim in the original patent must exist.

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In the present case, this was accomplished. One of the most commonly asserted "errors" in support of a broadening reissue is the failure to appreciate the full scope of the invention during the prosecution of the original patent application (Hester, 142 F.3d at 1479-80). That is the case here. And, as the Federal Circuit held in Ball, the error can be the undue limitation of the claims of the original patent resulting from a limitation (there requiring a plurality of feedlines), inserted into the pre-amendment application claims to secure allowance over the prior art. (See Ball, 729 F.2d at 1432-33 and 1438).

The second step involves a comparison of the reissue claim under consideration and the corresponding *pre-amendment application claim*. There are three possible scenarios in this analysis. A convenient summary is provided in In re Clement:

- a. If the reissue claim is as broad as or broader than the canceled or amended claim in all aspects, then the recapture rule bars the claim.
- b. If the reissue claim is narrower in all aspects than the canceled or amended claim, then the recapture rule does not apply.
- c. If the reissue claim is broader in some aspects, but narrower in others, relative to the canceled or amended claim, then the recapture rule applies and analysis must be carried out as to whether various aspects of the claim (those that are broader and those that are narrower) are "germane" to any prior art rejection.

During the interview of August 13, we referred to scenario (b) above as the "Gateway Test". If the facts are in line with scenario (b), then the recapture inquiry ends; it is not necessary to do any further analysis. This is set forth clearly at MPEP §1412.02, page 1400-15. Definitive statements regarding this Gateway Test also appear in Clement (as noted above) and Ball Corp.

The rather lengthy and complex analysis with regard to scenario (c) above (which is not necessary to conduct if the Gateway Test of scenario (b) is satisfied), is the subject matter of the "Two Step Test..." at MPEP 1400-13. This is also what forms the bulk of the case law cited by the Patent Office in the outstanding Final Office Action (Clement; Ball Corp.). In Clement and Ball Corp., the reissue claims under consideration were in some ways broader and in some ways narrower than the original patent claims, triggering the lengthy and detailed analysis under scenario (c). In Hester, it was determined that the typical "error" (not appreciating the full scope of the invention during prosecution of the original patent application) was not present in view of the facts there.

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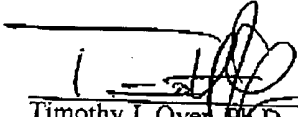
Applicants' claims are removed from recapture analysis by the "Gateway Test"

The present reissue application includes only one independent composition claim, i.e., claim 581 (the other three independent claims are to articles, i.e., claims 597, 620 and 674).

Comparing independent composition claim 581, as proposed for amendment (or even as currently pending), with the corresponding pre-amendment application composition claims I and 11 (prior to the amendment filed by Applicants on June 21, 1999), it is clear that claim 581 is narrower in all aspects than either of claims I or 11. As previously noted, pre-application composition claims I and 11 were the only claims that were substantively amended during the prosecution leading to the original patent.

If, for any reason, the Examiner is of the opinion that further correspondence with the Applicants' representative would expedite prosecution, or if any other information might be helpful, the Examiner is kindly invited to contact the undersigned at 617.573.7851.

Respectfully submitted,



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